

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:

Enrofloxacin for Poultry: Withdrawal
of Approval of Bayer Corporation's
New Animal Drug Application
(NADA) 140-828 (Baytril)

FDA DOCKET: 00N-1571
DATE: May 10, 2002

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Center for Veterinary Medicine's Submission of Additional Documents Pursuant to the
Administrative Law Judge's April 26, 2002, Order

Background

After receipt of Bayer's Motion to Compel (and even before the Judge's April 26, 2002, Order), the Center for Veterinary Medicine ("CVM" or "the Center") began searching the new animal drug application (NADA) and investigational new animal drug (INAD) files in the Center's Document Control Unit, for any additional documents required to be produced under 21 C.F.R. §12.85. The Center has identified the attached documents as responsive to the Administrative Law Judge's Order, and required to be submitted by 21 C.F.R. §12.85. Further, the Center has attached documents that it has obtained subsequent to its initial submission pursuant to Section §12.85 on February 14, 2002. These documents are submitted pursuant to the Administrative Law Judge's April 26, 2002, Order and 21 C.F.R. §12.85(a)(2). The Center is still investigating whether

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there are any other mistakes in its initial submission that require correction, and anticipates filing a Motion to Correct its Submission under Section 12.85 as soon as the investigation is completed.¹

1. Documents Required by 21 C.F.R. §12.85(a)(1)

The Center now believes that it has already complied fully with the requirements of 21 C.F.R. §12.85(a)(1). That section requires submission of "relevant portions of the administrative record of the proceeding". 21 C.F.R. §10.3 defines the "administrative record" as "the documents in the administrative file of a particular administrative action on which the Commissioner relies to support the action." The Notice for Opportunity for a Hearing² included 75 references³ which are the documents on which the Center relied in proposing to withdraw the approval of Baytril for use in poultry, and that constitute the administrative record of the proceeding for purposes of Section 12.85(a)(1). These documents were made part of Docket 00N-1571 on October 31, 2000.

2. Documents Required by 21 C.F.R. §12.85(a)(2)

CVM has determined that the attached documents contain factual information which relate to the issues involved in the hearing, and are required to be submitted under 21 C.F.R. §12.85(a)(2). These documents have been redacted where appropriate to delete deliberative or other exempt information. In addition, CVM redacted these documents to avoid posting confidential information on the public docket. Unredacted copies of the

¹ In Bayer's Objections to CVM's §12.85 Submission and Motion to Compel Additional Submission, Bayer stated, "Bayer also has some objections to certain documents in CVM's §12.85 submission which are incomplete or illegible. Bayer will work with CVM's counsel to address these without burdening the Administrative Law Judge." Bayer's Motion at 2. On May 9, 2002, counsel for Bayer faxed its identification of illegible documents to CVM's counsel. The list identified two documents. CVM will, of course, provide more legible copies of these to the record, the Administrative Law Judge and the participants.

² 65 Fed. Reg. 64954 (October 31, 2000).

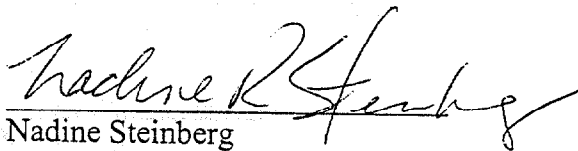
³ Reference 2 itself contains over 100 supporting documents.

documents containing confidential commercial or trade secret information are also being provided in full to the Administrative Law Judge. For those documents that contain confidential commercial or trade secret information of a sponsor other than Bayer, the Center does not object to Bayer seeking disclosure of such documents under a protective order issued by the Administrative Law Judge.⁴ CVM located these documents in NADA and INAD files in the Center's Document Control Unit. CVM believes that the documents in the seven categories listed in Bayer's Motion that exist outside of the NADA and INAD files have either already been produced or are exempt from production under 21 C.F.R. §12.85(a)(2) (e.g., internal memoranda reflecting the deliberative process).⁵ The Center is also submitting additional documents that fall under Section 12.85(a)(2) that the Center has located or obtained subsequent to its February 15, 2002, submission to the docket.

Conclusion

CVM respectfully submits the attached documents to the Docket pursuant to the Administrative Law Judge's April 26, 2002, Order.

Submitted this 10th day of May, 2002, by:



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⁴ 21 C.F.R. §10.20(j) authorizes the Administrative Law Judge to disclose this information to the extent necessary for the proper conduct of the hearing.

⁵ Documents identified in the NADA and INAD files that contain relevant information but that consist of deliberative process material have not been submitted.

Enrofloxacin Hearing
Docket No: 00N-1571

CERTIFICATE OF SERVICE

I hereby certify that an original and a copy of the foregoing Center for Veterinary Medicine's Submission of Additional Documents was hand delivered this 10th day of May, 2002, to:

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

I also certify that a copy of the accompanying transmittal pleading has been hand delivered, this 10th day of May, 2002, to:

The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

I also certify that a copy of the accompanying transmittal pleading was e-mailed and also mailed, postage prepaid, this 10th day of May, 2002, to:

Robert B. Nicholas
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005

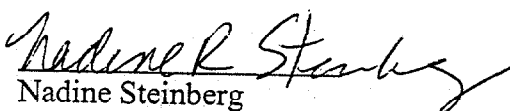
and

Kent D. McClure
Animal Health Institute
1325 G Street, NW, Suite 700
Washington, DC 20005

I also certify that a copy of the accompanying transmittal pleading was e-mailed,
this 10th day of May, 2002, to:

Judge Daniel Davidson
The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
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Dated: 5/10/02


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